National Nutritional Foods Association

TESTIMONY OF DAVID R. SECKMAN
BEFORE
The Subcommittee on Human Rights & Wellness
of the House Government Reform Committee
U. S. HOUSE OF REPRESENTATIVES
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Chairman Burton and Honorable Members of the Subcommittee on Human Rights & Wellness, thank you for the opportunity to address you as a representative of the dietary supplement industry. I am David Seckman, executive director and CEO of the National Nutritional Foods Association (NNFA). NNFA was founded in 1936 and is the oldest and largest trade association in the natural products industry. We represent the interests of more than 5,000 retailers, manufacturers, suppliers and distributors of health foods, dietary supplements and related items.

The Committee has asked that I address the status of dietary supplements in the U.S. as we reach the 10-year milestone of the law that governs these diverse products, the Dietary Supplement Health and Education Act (DSHEA) of 1994. I think the Committee has chosen an appropriate anniversary to revisit the law. In my experience, when a law has been on the books for 10 years ample evidence accumulates as to what is working and what is not. In regard to DSHEA, its enactment may have occurred 10 years ago, but much of its key implementation has only happened within the past 18 months.

Because dietary supplements are often viewed in regard to their safety, quality and efficacy, my testimony today will address how well the law has supported and is being applied in these three broad categories. Since the law underlies all that we will discuss here today, let me start with DSHEA.

The Dietary Supplement Health and Education Act was unanimously passed in 1994 to balance the American consumer's growing interest in health maintenance with the preservation of public safety. This legislation improved consumer access to dietary supplements and information about these products. It also increased consumer protection against unsafe products and false and misleading claims. In addition, it required supplement manufacturers to submit evidence of the safety of their products and the scientific basis for claims.

DSHEA is often mischaracterized as lessening the Food and Drug Administration's ability to regulate supplements. In fact, the enactment of DSHEA provided the FDA, the primary

agency that regulates supplements, with increased enforcement powers by establishing new labeling and potency standards. Briefly, under DSHEA, the FDA has the power to:

- Seize dietary supplements that pose an "unreasonable or significant risk of illness or injury" [Section 402 (f)].
- Stop the sale of an entire class of dietary supplements if they pose an imminent public health hazard [Section 402 (f)].
- Require dietary supplements to meet strict manufacturing guidelines (Good Manufacturing Practices), including potency, cleanliness, and stability [Section 402 (g)].
- Stop a new dietary ingredient from being marketed if the FDA does not receive enough safety data in advance [Section 413].
- Refer for criminal action any company that sells a dietary supplement that is toxic or unsanitary [Section 402 (a)].
- Obtain an injunction against the sale of a dietary supplement that has false or unsubstantiated claims [Section 403 (a), (r6)].

In evaluating the effectiveness of any law, there are two critical steps that must follow its enactment: implementation and enforcement. Laws only work if their provisions are put into practice and the failure to abide by them is monitored and punished. In regard to DSHEA specifically, and for a number of reasons, this law has never been fully implemented or adequately enforced.

Although I will highlight specific instances where the FDA has not fully implemented DSHEA, let me say that the agency, under the leadership of Commissioner McClellan, has made progress, particularly in regard to enforcement. But there is still much more to be done.

Quality

Having standards in place that help to ensure that what is on a product label is actually in the product is essential. Although manufacturers of dietary supplements are currently required to adhere to standards developed for foods, DSHEA provided for the establishment standards tailored to dietary supplements. Such standards are called good manufacturing practices, or GMPs. GMP standards would require manufacturers to evaluate the identity, purity, quality, strength, and composition of their dietary ingredients and dietary supplements. And in fact the FDA has proposed a regulation for dietary supplement GMPs that would do just that. However, the publication of this rule last year took more than nine years from the passage of the law that allowed for it. I do not have an answer as to why this took so long, nor have I heard an explanation from the FDA. In fact, I testified last year at a Senate hearing where an FDA panelist was asked and had no answer to explain the delay.

Certainly, the dietary supplement industry did not present an obstacle to establishing a GMP regulation. Quite the opposite. The leading trade associations and their members actually

encouraged and welcomed its release. Further, in a substantive demonstration of industry support for a good manufacturing practices framework for dietary supplements, my organization created its own certification program five years ago.

I understand that the FDA is reviewing comments regarding the proposed rule in order to finalize it. While industry, including NNFA, has some concerns with it, such as unrealistic costs for to implement the rule and its lack of flexibility, we believe these can be addressed while still maintaining the integrity of the final regulation. We trust that the FDA finds merit in our comments and will address our areas of concern when it issues a final regulation, hopefully this year.

Safety

While I want to discuss specific examples of how DSHEA has been applied when an issue of safety has arisen, I would first like to put this issue in perspective. Dietary supplements are far safer than most common foods and drugs that consumers use without a second thought. For instance, the common pain reliever ibuprofen is responsible for more than 17,000 deaths annually[1]. Prescription drugs, for all the testing they go through and copious usage directions that are issued with them, are estimated to be one of the top five leading causes of death in the U.S. at more than 106,000 annually [2]. Illnesses from tainted foods kill 5,000 Americans killed each year[3].

One reason that supplement safety is questioned is because few can agree on accurate sources for statistical information about their use. Even so, the FDA's most recent adverse event estimates for dietary supplements are 1,214 in a given year[4]. Comparatively, the FDA received more than 300,000 adverse reports about drugs [5] over the same 12 month period. So, using the FDA's own data, adverse events related to supplements represent less than half-of-one percent of drug adverse events.

Critics of DSHEA claim the number of adverse events reported would be much higher were a different reporting system in place. The FDA has just begun implementing an extensively revamped reporting system for dietary supplements that should yield more accurate data about potential problems with these products and others. This new system should be given a chance to work. The industry supports continuing efforts that will provide a constructive and impartial representation of dietary supplement safety.

As I mentioned earlier, there are several provisions in DSHEA that grant the FDA the authority to ensure that only safe products stay on the market or reach it in the first place. In regard to the former, for a number of years, the agency has questioned its ability under DSHEA to effectively remove a product it believes presents a safety risk. Now, for the first time since DSHEA was passed, the FDA has exercised such authority under this law by banning a product it believes presents an "unreasonable risk of illness or injury" to consumers. I am talking of course about ephedra.

The FDA took literally years to weigh the considerable safety evidence for and against removing ephedra from the marketplace. Keep in mind that banning a product is not the

agency's only option. The FDA could have also regulated dosage and mandated warning labels on these products. Although critics of DSHEA have claimed it eviscerated the FDA's enforcement powers, the agency's most recent actions in regard to ephedra prove otherwise.

Another provision of DSHEA which the agency has just implemented is in regard to pre-market approval for a new dietary ingredient. This very recent action involves androstenedione or "andro." The FDA defines a new dietary ingredient as one not marketed in the U.S. prior to DSHEA's passage in October of 1994. In most cases, the law requires that at least 75 days prior to selling any product containing a new dietary ingredient, manufacturers or distributors must submit to the FDA information that indicates the ingredient is "reasonably" expected to be safe. The FDA contends that no such notification was received in the case of andro and that products containing it are adulterated and their marketing prohibited under DSHEA.

This example illustrates again that the law works. But it also again begs the question of what took the FDA so long to take action. It was not because they were unaware that some had questioned andro's dietary supplement status. FDA has been asked for several years by both industry and lawmakers to determine whether andro products are actually dietary supplements as defined by DSHEA, but received no response.

In summary, what both theses actions, which pertained to different provisions in DSHEA, demonstrate is that the law does not prevent the FDA from taking action it deems necessary.

Efficacy

In passing DSHEA Congress acknowledged that there may be a positive relationship between sound dietary practice and good health, and that, although further scientific research is needed, there may be a connection between dietary supplement use, reduced health-care expenses, and disease prevention. The Office of Dietary Supplements was established as a result of DSHEA to stimulate, coordinate and disseminate the results of research on the benefits and safety of dietary supplements in the treatment and prevention of chronic disease. NNFA agrees with the President's Commission on Dietary Supplement Labels that if fully-funded, "...ODS could play a valuable role in providing consumers with information about dietary supplements ...including [the] promotion of scientific studies on potential roles of dietary supplements in health promotion and disease prevention. Appropriations as authorized by DSHEA are essential if ODS is to meet [the] mandates of the Act."

The office, with NNFA's support, has begun funding research on botanical supplements through university-based research centers. Each of the ODS-funded centers will promote scientific discourse and provide the critical scientific mass necessary for sound studies on the efficacy and safety of botanical supplements. With the support of NNFA and other industry associations, the ODS' budget has grown from $69,000 when it was first created in the mid 1990s to $20 million in Fiscal Year 2003. NNFA supports future increases for funding.

Clearly, dietary supplements as a whole – not just vitamins and minerals – are beginning to get the research attention they deserve. Each year, more and more studies are published in

major medical journals that support the use of supplements for the treatment of specific conditions, prevention of diseases or for general nutritional enhancement. This is due, to an increasing extent, to funding from government agencies and offices, like ODS.

Examples of notable dietary supplement research include an article published in the *Journal of the American Medical Association (JAMA)*, where researchers concluded that every child and adult would benefit from taking vitamins daily [6]. A report in the journal *Nutrition* also recommended a daily vitamin for older adults, who often don't get proper nutrition from food [7]. These studies are particularly important because our research indicates that physicians often do not discuss supplementation with their older patients [8]. Other landmark studies include two published in *JAMA* relating to the delay and lessening of symptoms of Alzheimer's disease by patients who took the herb ginkgo and vitamins C and E [9, 10].

Not only has research demonstrated the health benefits of dietary supplements, it has also shown that they can reduce health-care costs by the billions of dollars. For instance, researchers at the University of California in San Francisco estimate that 310,000 fewer people would die from heart disease over a ten-year period if they ate folate-fortified foods and supplemented with B vitamins vs. eating only fortified foods [11]. Another study in a major medical journal reported that increased intakes of vitamin E, folic acid and zinc could save $20 billion annually in hospital costs by reducing heart disease, birth defects and premature death [12]. Another study published late last year that reported that if seniors took a multivitamin daily it could reduce health care costs by $1.6 billion annually [13]. Earlier I mentioned two studies showing the positive affect dietary supplements can have on Alzheimer's disease. This illness costs Americans $61 billion a year, in lost productivity from absenteeism of employees who care for family members with Alzheimer's and businesses that share health and long-term care costs [14]. Even a modest reduction in symptoms and delay of onset of this destructive disease can save billions of dollars.

Let me add that with Science increasingly validating the role dietary supplements play in maintaining health and preventing illness, that it makes sense that these products receive the same favorable IRS treatment as other recognized health expenses. To that end, we support passage of a bill introduced by Chairman Burton that would do just that, H.R. 2627, the Dietary Supplement Tax Fairness Act.

Additional Implementation and Enforcement

The FDA is not alone in enforcing and implementing DSHEA. The Federal Trade Commission also has regulatory authority over what supplement manufacturers can say about their products in advertising or on the Internet. For example, in recent years the FTC has invested substantial time and resources in cracking down on online supplement advertisers who disobey the law. While the industry applauds and supports these efforts, I would like to point out that supplements sold over the Internet account for only one percent of total dietary supplement sales. Attention paid to a small fraction of Internet supplement marketers who break the law is disproportionate to the actual problem. Nevertheless, the industry has been vocal in its support of the FTC's Internet sweeps and encourages their continuation.

In summary, DSHEA increased FDA enforcement authority to preserve consumer safety and mandated higher product standards. It also provided for more funding for supplement research that would validate their efficacy. The result is an increased ability by consumers to make informed personal health choices.

But to be effective, like any law, it needs to be implemented and enforced. The bottom line is that there is no issue with dietary supplements, be it quality, safety or efficacy, which cannot be addressed under the current regulatory and legal framework.

Finally, I will leave the Committee with three recommendations to improve the effectiveness of DSHEA. The first is to give the FDA the resources it needs to fully implement the law. This can be done through the appropriations process and through Passage of a new bill introduced in the Senate by Sens. Tom Harkin and Orrin Hatch, S. 1538, "The DSHEA Full Implementation and Enforcement Act." This bill would provide the FDA with the funding it needs to ensure that DSHEA is carried out as Congress intended. It would also increase funding for the National Institutes of Health's Office of Dietary Supplements. I understand that a companion bill is likely in the House and hope it you will support it.

The second is for the FDA to quickly finalize and begin enforcement of good manufacturing practices for dietary supplements. Although I believe the vast majority of dietary supplement manufacturers have implemented production procedures that meet or exceed what is currently required by law, a federal GMP regulation would bring all others into line, as well.

My final recommendation is this: Stop seeking legislative solutions to regulatory problems when it comes to DSHEA. Currently, there are six bills in Congress that will amend, augment or otherwise modify DSHEA in an attempt to fix perceived weaknesses in the law. Although we support the intent of some, I believe most would not have been introduced if the Food and Drug Administration had used its authority in a more timely manner to fully implement and enforce DSHEA.

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